Recommendations of Exclusion of Drugs on Category-II

156. PROF. C. LAKSHMANNA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Ministry of Health and Family Welfare has made recommendation recently to Department of Chemicals as well as Kelkar Committee for exclusion of certain drugs from Category II under existing price control as well as inclusion of certain drugs in category II;

(b) if so, when such a recommendation was sent;

(c) what are the names of drugs recommended for exclusion alongwith the basis and justification thereof;

(d) what are the names of drugs recommended for price control alongwith therapeutic indication of each;

(e) whether if Ministry of Health and Family Welfare has also recommended for shifting of drug from category I to II; and

(f) if so, what are the names of those drugs and the justification of such recommendation?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) to (f) On the basis of a review made by the Director General of Health Services, recommendations were made to the Department of Chemicals on 9th June, 1988 for the exclusion of Paracetamol from the purview of Category I, on account of its not being specifically anti-malarial, and Diazepam and other tranquillizers from the purview of Category II as tranquillizers may not be considered essential for price control. Reclassification of Rifampicin from Category I to Category II has also been recommended, the criterion being the high technology involved in the manufacture of the drug requires incentives for production.

Definition of principal drugs for price control

157. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state.

(a) what is the definition of principal drugs and in what manner this definition was applied for identification of drugs for price control;

(b) whether it is a fact that in the policy statement announced in December, 1986, all drugs required for National Health Programmes were to be covered under price control;

(c) whether Tetracycline Hcl. Hydrocortisone, Vitamin A, Folic Acid, Getamycin, Prednisolong, Iron drugs are principal drugs so far as control of blindness and Child & Maternal Health Programmes are concerned; and

(d if so, what is the differences between one and the other drug, when used for the diseases under these programmes?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) and (b) Essential Drugs distributed and used for specific diseases under eight National Health Programmes were identified for Price Control under the Drugs Price Control Order, 1987.

(c) and (d) Drugs for the Maternal and Child Health Programme are being evaluated for price control recommendations to the Department of Chemicals. Tetracycline Hcl. and Hydrocortisone are extensively used under the National Programme for Control of Blindness.

Permission for marketing of Ibuprofen and Mephenesin combination of FDA Gujarat

158. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state

(a) whether Ibuprofen in combination with Mephenesin has been allowed ointment from by the Food and Drug Authority Gujarat for marketing in the country;

(b) whether any study or clinical trial was done on this preparation;

(c) if so, what are the details thereof;

(d) what is the procedure for approval of such products and whether all those procedures have been followed;

(e) what are the names of the countries where such preparation is being marketed;

(f) whether it is a fact that drug authorities in States have refused to give permission for such preparation; and

(g) if so, what is Government policy in this regard?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) to (c) Central Drugs Standards Control Organisation has no information whether Ibuprofen in combination with Mephenesin has been permitted in ointment form by the Food & Drug Authority, Gujarat for marketing.

(d) and (e) As per the Guidelines on introduction of New Drugs combination of known drugs would fall under the definition of "New Drugs" and such permission to manufacture and market new drug is required to be granted by the Drugs Controller, India. However, the guidelines are not yet statutory and some States have been licencing certain combination of drugs for marketing.

(f) Central Drugs Standards Control Organisation has no information on the names of the countries where such preparation is being marketed.

(g) Government is making the guidelines statutory and permission to manufacture and market all types of combination products would be required to be obtained from the Drugs Controller, India based on the laid down guidelines once these guidelines become statutory.

Marketing of drug for TB

159. SHRI M. KADHARSHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the names of drugs cleared for marketing in the country for treatment of Tuberculosis by drugs Controller of India;

(b) whether it is a fact that a number of combinations of one or more drugs are being marketed in the country for the treatment of Tuberculosis;

(c) if so, what is the composition of these combinations;

(d) whether any of these combinations have been withdrawn from the market or are under process of withdrawal due to irrational combination; and

(e) if so, what are the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI MOTI LAL VORA): (a) The names of anti-tuberculosis drugs approved to marketing in the country are PAS, Capromycin sulphate Ethambutol, Ethionamide, INH, Morazinamide, Prothionamide, Pyrazinamide, Rifampicin, Thiacetazone, Terizidone and Cycloserine.

(b) and (c) The combination of drugs marketed in the country for the treatment of tuberculosis are:

1. Rifampicin 450 mg * INH 300 mg—strip of 4 capsules

2. Etnambutol 800 mg INH 300 mg—strip of 10 tablets